**Reviewer’s report**

**Title:** Study protocol of the RAND-study: a multicenter, prospective cohort study investigating response and adherence to first-line nilotinib treatment in chronic myeloid leukemia

**Version:** 1  
**Date:** 27 January 2014

**Reviewer:** Katia BB Pagnano

**Reviewer’s report:**

The present study will evaluate response and adherence in Intermediate and High risk CML patients treated with Nilotinib 300mg bid in front line. Factors that can contribute to adherence will be evaluated by quality of life questionnaires. Adherence will be evaluated using pill counts, with MEMS. Patients will be considered adherent if 90% of the medication prescribed was taken.

The study is well designed, and the methods to evaluate responses and adherence are adequate.

There are discretionary revisions that can improve the manuscript:

1. The primary end-point is CCyR at 12 months. Responses with Nilotinib in front line are faster and deeper, as demonstrated in ENESTnd trial (Kantarjian, 2011). In the ENEST most of patients will achieve this primary end-point at 6 months. A suggestion for this study is to consider as primary end-point the rate of MMR at 12 months.

2. The study will also measure Nilotinib plasma levels, but in the methods session the statistic analysis that will be used for comparison of patient’s plasma levels was not detailed.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

In last five years I received fees from Novartis Brazil as speaker